C3 contd

the first and the second active ingredients are present in quantities producing a mutual synergistic effect on the inhibition of the growth of *Malassezia furfur*.

REMARKS

Reconsideration of the captioned application as amended herewith is respectfully requested.

This preliminary amendment is filed concurrently with a continuing prosecution application ("CPA") in lieu of filing an appeal brief in response to the Office Action. This CPA and preliminary amendment are being filed via Express Mail on Monday, 3 December 2001. In view of the fact that the two (2) month period of response to the Notice of Appeal fell on a Saturday (1 December 2001), Applicants respectfully submit that this CPA and Preliminary Amendment are being timely filed on the next succeeding business day in accordance with 37 CFR §1.7 without need for an extension of time.

The Office Action rejected claims 1 – 5 as anticipated under 35 USC §102(b) by GB 2,256,139; rejected claims 1 – 14 under 35 USC §103 as unpatentable over United States Patent No. 5,456,851 to Liu ("Liu"), United States Patent No. 5,536,742 to Mason, ('Mason'), individually or in combination, and further in combination with United States patent No.: 5,688,496 to Fost ("Fost '496"), United States Patent No. 5,648,348 (Fost '348"), and United Staets Patent No. 5,164,375 to Vanmiddlesworth ('Vanmiddlesworth"). Claims 15 to 19 were added. Claims 1 - 19 remain pending in the application after entry of this amendment.

Claim 1 was amended to clarify that the surfactant is "other than a phospholipid." Support for this amendment may be found in the Specification as originally filed at, for example, page 10, Examples 1 and 2, and as such does not introduce new matter into the application under 37 CFR 1.121. New claims 15 to 18 are directed to subject matter found in original claims 2 - 5, respectively, but are dependent upon claim 6; accordingly, these claims do not introduce new matter into the application under 37 CFR 1.121. New claim 19 is directed to subject matter found in original claims 1 and 4 and Example 7 in the Specification on page 13, line 12 – page 15, last line, and as such does not introduce new matter into the application under 37 CFR 1.121.

For reasons unrelated to patentability, claim 6 was also amended to incorporate the language of independent claim 1, as originally filed, therein without narrowing the scope of claim 6.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned, "**Version with markings to show changes made**."

The Rejection of Claims 1 – 5 under 35 USC §102(b) as Anticipated by GB 2256139 Should Be Withdrawn

Claims 1 – 5 stand rejected under 35 USC §102(b) as anticipated by GB 2256139. Applicants respectfully disagree for the reasons that follow.

GB 2256139 expressly states that"[n]o surface active agents... are required thereby and additional side effect problems commonly associated with their use are thus avoided." Therefore, the compositions of GB 2256139 do not contain and expressly teach away from the use of any "surfactant other than a phospholipid", which is an element of claim 1.

According to the Office Action, the combination of phospholipids disclosed in GB 2256139 allegedly "meets the requirements of instant claims" because "phospholipids are known surfactants." Applicants respectfully submit that, in view of the clarification made to element (b) of claim 1, GB 2256139 does not disclose or suggest the use of any "surfactant other than a phospholipid" as claimed in claim 1.

Rejections under 35 USC §102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. In re Marshall, 198 USPQ 344 (CCPA 1978). In other words, to constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art. Id. The exclusion of a claimed element from a prior art reference is enough to negate anticipation under 35 USC §102 by that reference. Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 224 USPQ 409 (Fed. Cir. 1984).

Therefore, since GB 2256139 fails to disclose or suggest an element of Applicants' claim 1, i.e. a "surfactant other than a phospholipid', Applicants respectfully submit that the rejection of claim 1under 35 USC §102(b) has been overcome and should be withdrawn.

Claims 2 – 5, which are dependent upon claim 1 and incorporate all of its limitations therein, are likewise also patentable over GB 2256139 in view of the above.

GB 2256139 further fails to disclose or suggest the use of the claimed antifungal and the claimed phospholipid 'in quantities producing a mutual synergistic effect on the inhibition of the growth of Malassezia furfur" as claimed in claim 4. Therefore, since GB 2256139 also fails to disclose or suggest an element of Applicants' claim 4, i.e. use of the claimed antifungal and th claimed phospholipid 'in quantiti s producing a mutual synergistic effect on the inhibition of

the growth of Malassezia furfur", Applicants respectfully submit that the rejection of claim 4 under 35 USC §102(b) has further been overcome and should be withdrawn.

The Rejection of Claims 1 – 14 under 35 USC §103(a) as Being Unpatentable Over Liu and/or Mason, and Further Over Fost '496, Fost '348, or Vanmiddlesworth Should Be Withdrawn

Claims 1 – 14 stand rejected under 35 USC §103(a) as being unpatentable over Liu and/or Mason individually or in combination, further in combination with Fost '496, Fost '348, or Vanmiddlesworth. Applicants respectfully disagree for the reasons that follow.

As stated in the Office Action, both Liu and Mason neither disclose nor suggest the use of phospholipids, let alone the use of the particular amphoteric phospholipids as claimed in claim 1.

Applicants respectfully submit that there is neither a disclosure nor a suggestion in either Fost reference or Vanmiddlesworth to include the phospholipids disclosed in such references, respectively, in the antifungal-containing compositions of Liu or Mason. Moreover, given the fact that the compositions of Liu and Mason already include an antifungal component, Applicants respectfully submit that there is no disclosure or suggestion in either Liu or Mason to further include yet another antifungal compound, let alone the particular antibacterial/antifungal phospholipids of Fost '348 or Vanmiddlesworth.

In order to properly combine two references for purposes of reaching a conclusion of obviousness, there must be some teaching, suggestion, or inference in at least one of those references that would have directed one to combine the relevant teachings of such references. See Ex parte Levengood, 28 USPQ.2d 1300 (BPAI) and Ashland Oil v. Delta Resins and Refractories, Inc. 227 USPQ 657 (Fed. Cir 1985). Both the suggestion to make the claimed composition, as well as the reasonable expectation of success must be founded in the prior art and not in Applicant's specification. See In re Vaeck, 20 USPQ.2d 1438 (Fed. Cir. 1991).

Applicants further respectfully submit that the references cited in the Office Action neither disclose nor suggest the composition claimed herein, let alone the fact that such a composition would be effective in treating dandruff and seborrheic dermatitis and in inhibiting the growth of *M. Furfur.*

More specifically, Applicants discovered that an increased proportion of patients suffering from dandruff or seborrheic dermatitis responded to the novel claimed composition (see Specification, page 2, lines 1 – 14 and page 3, lin s 8 - 10). Applicants have also

unexpectedly found that the claimed combination exhibits superior synergistic properties against *M. furfur* in vitro as set forth in Example 7 on pages 13 – 15 of the Specification. (FIC values less than one are indicative of a synergistic interaction between the ketoconazole and the cocamidopropylphosphatidyl PG-dimonium chloride, which is commercially available as "Phospholipid PTC".) See new claim 19.

In sum, not only is there a lack of disclosure or motivation to combine the references as proposed in the Office Action, but also Applicants have unexpectedly found that the particular antifungal components and the particular amphoteric phospholipid components claimed herein possess superior, synergistic effects on the inhibition of *M. furfur* growth. In view of the above, Applicants respectfully submit that claim 1 is patentable over Mason and/or Liu and further in combination with either Fost reference and Vanmiddlesworth, and that the rejection of claim 1 under 35 USC §103(a) has been overcome and should be withdrawn.

Claims 2 – 14, which depend upon claim 1 and incorporate all of its limitations therein, are likewise patentable over Mason and/or Liu and further in combination with Fost '496, Fost '348, and Vanmiddlesworth, and that the rejection of these claims under 35 USC §103(a) has been overcome and should be withdrawn.

Moreover, claim 3, which is directed to a particular phospholipid, is neither disclosed nor suggested in either of the two Fost references. In particular, the phospholipids of these Fost references do not have the acyl group as does the claimed phospholipid.

In view of the fact that Applicants unexpectedly found that the claimed active ingredients unexpectedly possessed a synergistic effect on the growth of M. furfur as set forth above, Applicants respectfully submit that none of the cited references disclose or suggest the creation of a composition containing the claimed active ingredients in quantities producing "a mutual synergistic effect on the inhibition of the growth of Malassezia furfur" as claimed in claim 4.

Because none of the references disclosed the combination of the claimed antifungal with the claimed amphoteric phospholipid, let alone the above mentioned synergistic effect exhibited by such a combination, Applicants further respectfully submit that none of the prior art references disclose or suggest the percentage amount of each claimed component as set forth in claim 5.

In addition, in view of the fact that none of the prior art references disclosed or suggested the claimed composition of claim 1, Applicants further respectfully submit that the process for making such a composition set forth in claim 14 is also neither disclosed nor suggested in th prior art.

In view of the arguments set forth above for claim 1 and the additional arguments set forth above for the dependent claims, Applicants further respectfully submit that the rejection of claims 1 to 14 under 35 USC §103(a) has been overcome and should be withdrawn.

Conclusion

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

In the event that all of the claims are not in condition for allowance, Applicants respectfully request for an interview with the Examiner before the preparation of the next Office Action.

Respectfully submitted,

By: _____
Michele G. Mangini
(Attorney for Applicants)
Reg. No. 36,806
Dated: 3 December 2001

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2810
JAB 1267new.pre.amt

Version with Markings to Show Changes Made

IN THE CLAIMS:

The claims have been amended as follows:

1. (Twice Amended) A body or hair cleansing composition comprising

(a-1) one or more antifungals inhibiting fungal ergosterol biosynthesis as a first active ingredient,

(a-2) a amphoteric phospholipid as a second active ingredient, and

(b) at least one surfactant other than a phospholipid.

6. (Twice Amended) A composition [according to claim 1] comprising

(a-1) one or more antifungals inhibiting fungal ergosterol biosynthesis as a first active ingredient,

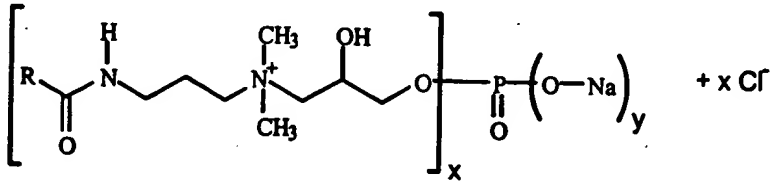
(a-2) a amphoteric phospholipid as a second active ingredient, and

(b) at least one surfactant, wherein said composition is formulated as a shampoo.

The following new claims were added:

-- (New) 15. The composition according to claim 6 wherein the antifungal inhibiting fungal ergosterol biosynthesis is an azole selected from the group consisting of ketoconazole, econazole, elubiol, miconazole, itraconazole, fluconazole, and a mixture thereof, or is an allylamine selected from the group consisting of terbinafine, naftifine, and a mixture thereof.--

-- (New) 16. The composition according to claim 6 wherein the phospholipid has the formula



wherein R represents a straight, saturated, mono-unsaturated or poly-unsaturated C7-19 alkyl group; x represents 1, 2, or 3, and x+y = 3; and mixtures thereof. --

-- (New) 17. The composition according to claim 6 wherein the first and the second active ingredients are present in quantities producing a mutual synergistic effect on the inhibition of the growth of *Malassezia furfur*.--

-- (New) 18. The composition of claim 6 wherein the first active ingredient is present in an amount ranging from about 0.1 % to about 2% (w/w) and the second active ingredient is present in an amount ranging from about 0.04% to about 10% (w/w), the amount of the latter being expressed as weight of phospholipid.--

-- (New) 19. The composition of claim 1 wherein the first active ingredient is ketoconazole and the second active ingredient is cocamidopropylphosphatidyl PG-dimonium chloride, and wherein the first and the second active ingredients are present in quantities producing a mutual synergistic effect on the inhibition of the growth of *Malassezia furfur*.--